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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,890	04/28/2000	ULRICH H. KOSZINOWSKI	203676	6925

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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/463,890	KOSZINOWSKI ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,37 and 40-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36, 37 and 40-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Paper filed 21 September 2007 in response to the Non-Final Office Action mailed 9 July 2007. Claims 36, 37 and 40-70 were considered in the 9 July Office Action. Claims 51-56 were amended in the 21 June Paper. Claims 36, 37 and 40-70 are pending and under consideration.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 101

Rejection of claims 51-56 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is **withdrawn** in view of the claim amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 37, 40, 42, 48, 51, 54, 57, 58, and 64-66 **stand rejected** under 35 U.S.C. 102(b) as being anticipated by Messerle et al. (1996) *J. Mol. Med.* 74:B8 (previously made of record). This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 3 and herein below in the response to Applicant's arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 41 **stands rejected** under 35 U.S.C. 103(a) as being unpatentable over Messerle et al. (*supra*). This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 5 and herein below in the response to Applicant's arguments.

Claim 43 **stands rejected** under 35 U.S.C. 103(a) as being unpatentable over Tomkinson et al. (1993) *J. Virol.* 67:7298-7306 in view of Messerle (*supra*). This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 6 and herein below in the response to Applicant's arguments.

Claim 44 **stands rejected** under 35 U.S.C. 103(a) as being unpatentable over Tomkinson et al. (*supra*) in view of Messerle et al. (*supra*), as applied to claim 43 herein above, and further

in view of Ehtisham et al. (1993) *J. Virol.* 67:5247-5252. This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 7 and herein below in the response to Applicant's arguments.

Claims 45-47, 49, 50, 52, 53, 55 and 56 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Messerle et al. (*supra*), as applied to claim 36 herein above, in view of Gage et al. (1992) *J. Virol.* 66:5509-5515. This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 9 and herein below in the response to Applicant's arguments.

Claim 59 **stands rejected** under 35 U.S.C. 103(a) as being unpatentable over Messerle et al. (*supra*) in view of Roizman et al. (1985) *Science* 229:1208-1214. This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 10 and herein below in the response to Applicant's arguments.

Claims 60-63 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Messerle et al. (*supra*) in view of Roizman et al. (*supra*) and further in view of Chen et al. (1987) *Mol. Cell. Biol.* 7:2745-2752. This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 11 and herein below in the response to Applicant's arguments.

Claims 67-70 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Messerle et al. (*supra*) in view of Luckow et al. (1993) *J. Virol.* 67:4566-4579 (previously made

of record). This rejection is maintained for the reasons set forth in the 9 July Office Action beginning at page 12 and herein below in the response to Applicant's arguments.

Response to Arguments

In response to the *prima facie* rejections of record, Applicant contends that the claims are not anticipated or obvious over the art because Messerle et al. does not teach or suggest a BAC comprising "an infectious herpes virus genomic sequence" according to the broadest reasonable interpretation of the claim limitation.

Specifically, Applicant submits that the Office Action's interpretation of the rejected claims is not consistent with the disclosure of the instant application. Applicant urges that the specification describes genomic sequences that are both necessary and sufficient for virus replication and packaging. Applicant further submits that use of the definite article "those" in reference to "parts of the genome of a virus" in the definition of "infectious herpes virus genomic sequence" at page 3 of the specification clearly indicates that the phrase "infectious herpes virus genomic sequence" does not encompass any part of a viral genome necessary for replication. Rather, according to Applicant, such language indicates that the phrase "infectious herpes virus genomic sequence" encompasses all sequences that are sufficient for viral replication and packaging.

These arguments are not persuasive. Applicant is reminded that Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). In the instant case, interpretation of the claim scope turns on whether one would construe the limitation "an

infectious herpes virus genomic sequence" as requiring that the virus genomic sequence comprised by the BAC have the capacity to generate an infectious herpes virus without the aid of any helper functions provided by nucleic acids outside of the BAC. It is noted that the claims themselves do not recite any functional limitation for the infectious herpes virus genomic sequence. Therefore, the functional properties of the virus genomic sequence comprised by the BAC are defined exclusively by the meaning of the phrase "an infectious herpes virus genomic sequence".

Based solely on the plain meaning of the claim limitation, one would clearly not conclude that the genomic sequence comprised by the BAC must be sufficient to generate infectious virus without the aid of exogenous sequence. The phrase "genomic sequence" clearly does not require that the BAC comprise the entire virus genome, and the broadest reasonable interpretation of "an infectious herpes virus genomic sequence" is any genomic sequence from an infectious herpes virus. Thus, the plain meaning of the phrase does not imply any function at all, but merely requires that the genomic sequence be obtained from an infectious herpes virus.

As discussed in the previous Office Action, the specification teaches, "The expression 'infectious viral genome sequences' within the meaning of the invention covers both the complete genome and those parts of the genome of a virus that are indispensable for replication and packaging in a host organism or host cell." Although the definition does specify that "infectious viral genome sequences" must at least be parts of the genome of a virus that are indispensable for replication and packaging, the definition does not require that all parts of the viral genome that are indispensable for replication and packaging must be comprised by a nucleic acid in order to be considered within the scope of "an infectious viral genome sequence".

Contrary to Applicant's assertion, use of the definite article "those" in reference to "parts of the genome of a virus" in the definition of "infectious herpes virus genomic sequence" does not require that all such sequences must be present in a single nucleic acid. The phrase can reasonably construed as encompassing any such part, rather than all such parts, and, as the former interpretation is broader, the claims must be construed accordingly. While Applicant's assertion that the specification describes genomic sequences that are both necessary and sufficient for viral replication and packaging, the disclosure of those embodiments does not limit the claims to only those embodiments.

Applicant further quotes a portion of sentence from the paragraph bridging pages 2 to 3 of the specification which states, "at least those parts of the genome of a virus that are required for replication and packaging" and contends that the phrase "at least those parts" clearly indicates a specific defined subset of all of the sequences comprising the herpes virus genome required for replication and packaging.

This argument is not persuasive. The passage cited by Applicant reads in full, "It is the object of the present invention to provide recombinant **vectors** which make it possible to introduce the complete genome, or at least those parts of the genome of a virus that are required for replication and packaging…" (Emphasis added.) The passage clearly does not require that all "parts of the genome of a virus that are required for replication and packaging" be comprised within a single BAC as Applicant contends the claims must be construed. It is clear from the use of the plural "vectors" that the introduction of those parts of the genome of a virus that are required for replication and packaging might be accomplished with more than one vector.

Applicant notes that the term "infectious" is used interchangeably with the term "replication-capable" in the instant application, which, according to Applicant, further evidences that the phrase "infectious herpes virus genomic sequence" encompasses sequences that are sufficient for virus replication.

This argument is not persuasive. It is first noted that the question is not whether the phrase, "infectious herpes virus genomic sequence" encompasses sequences that are sufficient for virus replication. The question is whether the phrase excludes sequences that are necessary for virus replication but not sufficient, by themselves, to provide virus replication. Although the specification does equate infectious with replication-capable in the second full paragraph on page 5, this is in the context of producing infectious virus in eukaryotic cells. The passage is not discussing the minimum requirements of a BAC vector according to the invention and the passage does not indicate that the term “infectious” must always be construed as “replication-capable” in the instant application. The explicit definition of "infectious viral genome sequences”, according to the broadest reasonable interpretation thereof, does not require that all sequences necessary for replication of the virus be present in a single BAC. Furthermore, there is nothing in the application as a whole that requires “an infectious herpes virus genomic sequence” to comprise all elements of a virus genome such that it is capable of providing replication capable virus by itself. Therefore, the limitation must be construed as encompassing “parts of the genome of a virus that are indispensable for replication and packaging in a host organism or host cell” irrespective of whether the sequence as a whole is sufficient for replication and packaging.

Although Applicant correctly points out that neither of the plasmids described by Messerle et al. were capable of producing infectious virus when transfected alone, the instant

claims, construed as broadly as reasonable in light of the specification, do not require that the BAC has that property. The ability of the BAC vectors to produce infectious virus evidences that each of the vectors comprise "parts of the genome of a virus that are indispensable for replication and packaging". Therefore, for the reasons stated in the previous Office Action, the BACs of Messerle et al. anticipate the instant claims or, in view of the secondary references, render obvious, the instant claims. Therefore, the claims stand properly rejected under 35 USC § 102 and 35 USC § 103 as anticipated by or obvious over the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M Sullivan/
Primary Examiner
Art Unit 1636